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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fisher's Lane
Room 1061
Rockville, MD 20857

Re: Docket Nos. 92N-0297 and 88N-0285

TO WHOM IT MAY CONCERN:

This letter serves as the response from a group of Hemophilia Treatment Centers (HTCs), whom I represent, to the Final Rule which would amend the Prescription Drug Marketing Act of 1987; Prescription Drug Amendments of 1992; Policies, Requirements, and Administrative Procedures. This Final Notice was published in the Federal Register on December 3, 1999 (64 Fed. Reg. 232, 67720-67763) under the above referenced Docket Number.

Of major concern is the proposed definition of "Health care entity". As proposed, a health care entity could not simultaneously be a health care entity and distribute blood derivative products such as hemophilia clotting factor to non patients. Such a scenario could have serious implications for patient access to clotting factor.

HEMOPHILIA

Hemophilia is a hereditary bleeding disorder that predominantly affects males. Persons with hemophilia lack one or other protein, known as factors, that prevents their blood from forming clots which can lead to prolonged bleeding. This prolonged bleeding, left untreated or under treated, leads to joint damage or even death. Treatment of hemophilia is primarily through the administration of clotting factor to replace the factor which the affected individual is lacking.

The most significant cost faced by the patient with hemophilia is the cost of clotting factor concentrate. At current market prices, an adult person with moderate to severe hemophilia will spend approximately $100,000 per year on clotting factor and a pediatric patient about half that. This amount would be to cover routine outpatient usage. On an

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inpatient basis a person with hemophilia could easily exceed $100,000 on minimal stay in the hospital.

IMPLEMENTATION OF THE PROPOSED DEFINITION WILL ADVERSELY AFFECT CURRENT DISTRIBUTION AND PATIENT ACCESS TO CLOTTING FACTOR

Given the expense of having an inventory of clotting factor, many hospitals opt not to stock significant amounts of this drug. Instead they depend on specialty institutions such as blood banks or HTCs[1] to provide them with the clotting factor they need, when they need it. This system has worked effectively and has allowed persons with hemophilia to have access to treatment in a timely and cost efficient manner. This is especially important as many individuals with hemophilia are Medicaid and Medicare beneficiaries.

The issue becomes, not whether hospitals or other health care entities could obtain clotting factor from other sources, but whether such sources could provide the factor to the hospitals in the most efficient manner possible.

RECOMMENDATION

Current distribution channels that allow certain health care entities to distribute clotting factor to non patients has worked well. Patients have been able to get access to their life saving medication and placing restrictions on this existing system should be avoided.

Thank you for the opportunity to comment on this important issue. I appreciate your consideration of our position and if you have any questions, please call me at 301-528-5414.

Sincerely,

Derek Robertson

[1]Hemophilia Treatment Centers (HTCs) are federally funded centers of excellence that provide a range of comprehensive services to persons with hemophilia. There are just under 150 HTCs across the contiguous United States, Alaska, Hawaii, Guam and Puerto Rico. While not many HTCs distribute clotting factor, some do provide this critical service to hospitals and other heath care entities within their service area.